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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,189	01/16/2002	Berish Rubin	Rubin-201-KGB	6280
7590 Peter I. Bernstein Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			EXAMINER MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/050,189

Applicant(s)

RUBIN ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Upon reconsideration, the previous suspension of this application is withdrawn. As discussed below, Applicants declaration filed under 37 CFR 1.131 is not sufficient to antedate the Slaughaupt PG Publication No. 2002/0169299. This action also contains new grounds of rejection over claims 7, 8 and 13. This action is made non-final.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Slaughaupt (US 2002/0169299; cited in the IDS).

Slaughaupt (pages 10-12) teaches methods for detecting the presence of a mutation in the IKAP gene (referred to therein as the "IKBKAP" gene). In particular, Slaughaupt teaches methods which detect the presence of the T to C substitution at position 6 in the donor splice site of intron 20 and methods which detect the presence of a G to C transversion in exon 19, which results in an arginine to proline substitution at amino acid position 696 (referred to therein as nucleotide position 2397; see page 1, column 2). Slaughaupt teaches that the presence of each of these mutations is associated with the occurrence of FD (page 11). With respect to claims 5 and 6,

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Slaughaupt teaches that the nucleic acid to be analyzed is obtained by PCR amplification (page 4, column 2) and that the mutation may be detected by SSCP analysis (page 5, column 2). Accordingly, the method of Slaughaupt anticipates the claimed invention.

Response to Remarks / Declaration:

The declaration filed on May 12, 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Slaughaupt reference.

The Slaughaupt reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, **the reference can only be overcome by establishing priority of invention through interference proceedings.** See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Regarding interference proceedings, Applicants attention is directed to MPEP 2304.02 and 37 CFR 41.202, set forth in part below:

§ 41.202 Suggesting an interference.

(a) Applicant. An applicant, including a reissue applicant, may suggest an interference with another application or a patent. The suggestion must:

- (1) Provide sufficient information to identify the application or patent with which the applicant seeks an interference,
- (2) Identify all claims the applicant believes interfere, propose one or more counts, and show how the claims correspond to one or more counts,

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(3) For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a),

(4) Explain in detail why the applicant will prevail on priority,

(5) If a claim has been added or amended to provoke an interference, provide a claim chart showing the written description for each claim in the applicant's specification, and

(6) For each constructive reduction to practice for which the applicant wishes to be accorded benefit, provide a chart showing where the disclosure provides a constructive reduction to practice within the scope of the interfering subject matter.

(b) Patentee . A patentee cannot suggest an interference under this section but may, to the extent permitted under § 1.99 and § 1.291 of this title, alert the examiner of an application claiming interfering subject matter to the possibility of an interference.

(c) Examiner . An examiner may require an applicant to add a claim to provoke an interference. Failure to satisfy the requirement within a period (not less than one month) the examiner sets will operate as a concession of priority for the subject matter of the claim. If the interference would be with a patent, the applicant must also comply with paragraphs (a)(2) through (a)(6) of this section. The claim the examiner proposes to have added must, apart from the question of priority under 35 U.S.C. 102 (g):

(1) Be patentable to the applicant, and

(2) Be drawn to patentable subject matter claimed by another applicant or patentee.

(d) Requirement to show priority under 35 U.S.C. 102(g) .(1) When an applicant has an earliest constructive reduction to practice that is later than the apparent earliest constructive reduction to practice for a patent or published application claiming interfering subject matter, the applicant must show why it would prevail on priority.

(2) If an applicant fails to show priority under paragraph (d)(1) of this section, an administrative patent judge may nevertheless declare an interference to place the applicant under an order to show cause why judgment should not be entered against the applicant on priority. New evidence in support of priority will not be admitted except on a showing of good cause. The Board may authorize the filing of motions to redefine the interfering subject matter or to change the benefit accorded to the parties.

(e) Sufficiency of showing . (1) A showing of priority under this section is not sufficient unless it would, if un rebutted, support a determination of priority in favor of the party making the showing.

(2) When testimony or production necessary to show priority is not available without authorization under § 41.150(c) or § 41.156(a), the showing shall include:

(i) Any necessary interrogatory, request for admission, request for

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production, or deposition request, and

(ii) A detailed proffer of what the response to the interrogatory or request would be expected to be and an explanation of the relevance of the response to the question of priority.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slaughaupt (US 2002/0169299; cited in the IDS).

Slaughaupt (pages 10-12) teaches methods for detecting the presence of a mutation in the IKAP gene (referred to therein as the "IKBKAP" gene). In particular, Slaughaupt teaches methods which detect the presence of the T to C substitution at position 6 in the donor splice site of intron 20 and methods which detect the presence of a G to C transversion in exon 19, which results in an arginine to proline substitution at amino acid position 696 (referred to therein as nucleotide position 2397; see page 1, column 2). Slaughaupt teaches that the presence of each of these mutations is associated with the occurrence of FD (page 11). The reference also teaches that the nucleic acid to be analyzed is obtained by PCR amplification (page 4, column 2). Slaughaupt exemplifies primers for amplifying nucleic acids to detect the T to C substitution at position 6 in the donor splice site of intron 20 and the G to C transversion

in exon 19 (see page 12, col. 1). Slaughter does not exemplify primers consisting of the sequences of presently claimed SEQ ID NO: 6-9.

However, Slaughter does teach the genomic sequence of the IKAP gene (see Figure 6 therein) and teaches that the cDNA for this sequence was known in the art at the time the invention was made (see page 10). Given the disclosure of Slaughter of the location of the 2 mutations within the IKAP gene, the disclosure of the genomic and cDNA sequences flanking the 2 mutations, and the disclosure of the use of PCR primers to amplify nucleic acid sequences containing the 2 mutations, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have generated additional primers, including the primers of present SEQ ID NO: 6-9, in order to have facilitated the detection of the intron 20 splice site and exon 19 mutations. Designing primers which are equivalents to those taught in the art is routine experimentation. The parameters and objectives involved in the selection of primers were well known in the art at the time the invention was made. Moreover, software programs were readily available which aid in the identification of conserved and variable sequences and in the selection of optimum primer pairs. The prior art is replete with guidance and information necessary to permit the ordinary artisan to design additional primers for the amplification of IKAP sequences containing the FD associated mutations in the intron 20 splice site and exon 19. As discussed above, the ordinary artisan would have been motivated to have designed additional primers for amplifying IKAP sequences so as to have provided additional primers which could be used to amplify and detect the FD mutations in the intron 20 splice site and exon 19. Further, the

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ordinary artisan would have had more than a reasonable expectation of success of obtaining additional primers for amplifying IKAP sequences. Thus, for the reasons provided above, and in the absence of evidence to the contrary, the primers of present SEQ ID NO: 6-9 and the use of these primers in methods for detecting the FD mutations in intron 20 and exon 19 would have been obvious to one of ordinary skill in the art.

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slaughaupt in view of Ahren (The Scientist. July 1995. 19 (155): 20-24).

The teachings of Slaughaupt are presented above. Slaughaupt does not teach packaging primers, and particularly primers consisting of present SEQ ID NO: 6-9, in kits.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, Ahren discloses the general concept of kits for performing nucleic acid detection methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay and allows investigators to save time and money (see for example page 23).

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers for amplifying the IKAP sequences containing the intron 20 splice site mutation and exon 19 mutation, and particularly primers consisting of SEQ ID NO: 6-9, in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art wishing to amplify IKAP

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sequences and detect the presence of the intron 20 splice site and exon 19 mutations associated with FD.

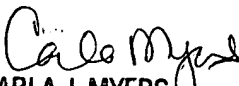
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carla Myers

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CARLA J. MYERS
PRIMARY EXAMINER